

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Bismuth Subnitrate (with Mineral Oil) Formulation

Version 5.2      Revision Date: 01/21/2026      SDS Number: 5060440-00016      Date of last issue: 12/06/2025  
Date of first issue: 10/17/2019

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### SECTION 1. IDENTIFICATION

Product name : Bismuth Subnitrate (with Mineral Oil) Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 37 McCarville Street  
Charlottetown, PE C1E 2A7  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**  
P314 Get medical attention if you feel unwell.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Bismuth hydroxide nitrate oxide	Bismuth sub-nitrate	1304-85-4	$\geq 60 - < 80$ *
White mineral oil (petroleum)	Paraffinum liquidum	8042-47-5	$\geq 10 - < 30$ *
Fatty acids, C14-26, aluminum salts	Aluminum Stearate	97404-28-9	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure.  
No information available.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

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- Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Metal oxides  
Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the
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environment.  
Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.  
Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist - Inhalable dust)	5 mg/m <sup>3</sup>	CA QC OEL
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable)	1 mg/m <sup>3</sup> (Aluminum)	CA BC OEL
		TWAEV (respirable aerosol fraction)	5 mg/m <sup>3</sup>	CA QC OEL
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Filter type : Combined particulates and organic vapor type  
Hand protection :  
Material : Chemical-resistant gloves

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Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	ointment
Color	:	White to light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available

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Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	None known.
Incompatible materials	:	None.
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

#### **Bismuth hydroxide nitrate oxide:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials
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Acute inhalation toxicity : LC50 (Rat): > 5.07 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
Remarks: Based on data from similar materials

### White mineral oil (petroleum):

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### Fatty acids, C14-26, aluminum salts:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Bismuth hydroxide nitrate oxide:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439

Result : No skin irritation

#### White mineral oil (petroleum):

Species : Rabbit  
Result : No skin irritation

#### Fatty acids, C14-26, aluminum salts:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431

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Remarks : Based on data from similar materials

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials

Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### **Bismuth hydroxide nitrate oxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

#### **White mineral oil (petroleum):**

Species : Rabbit  
Result : No eye irritation

#### **Fatty acids, C14-26, aluminum salts:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

### Respiratory or skin sensitization

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **Bismuth hydroxide nitrate oxide:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

#### **White mineral oil (petroleum):**

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

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### Fatty acids, C14-26, aluminum salts:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Bismuth hydroxide nitrate oxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

#### White mineral oil (petroleum):

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

#### Fatty acids, C14-26, aluminum salts:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

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### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **White mineral oil (petroleum):**

Species : Rat  
Application Route : Ingestion  
Exposure time : 24 Months  
Result : negative

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Bismuth hydroxide nitrate oxide:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

#### **White mineral oil (petroleum):**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Fatty acids, C14-26, aluminum salts:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test

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Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

### Components:

#### Bismuth hydroxide nitrate oxide:

Target Organs : Central nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### White mineral oil (petroleum):

Species : Rat  
LOAEL : 160 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

Species : Rat  
LOAEL :  $\geq 1$  mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 4 Weeks  
Method : OECD Test Guideline 412

#### Fatty acids, C14-26, aluminum salts:

Species : Rat  
:  $\geq 1000$  mg/kg  
Application Route : Ingestion  
Exposure time : 42 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Bismuth hydroxide nitrate oxide:

Ingestion : Target Organs: Blood

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Symptoms: Methaemoglobinemia  
Target Organs: Central nervous system  
Symptoms: Neurological disorders

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Bismuth hydroxide nitrate oxide:**

- Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 137 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 137 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 137 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 137 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201

##### **White mineral oil (petroleum):**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d

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ic toxicity)

### Persistence and degradability

#### Components:

##### White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

##### Fatty acids, C14-26, aluminum salts:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 81.2 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### Fatty acids, C14-26, aluminum salts:

Partition coefficient: n- : log Pow: > 7  
octanol/water                      Remarks: Calculation

### Mobility in soil

No data available

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste  
handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

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Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

AICS	:	not determined
CA. DSL	:	not determined
IECSC	:	not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA AB OEL / STEL	:	15-minute occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA	:	Time-weighted average exposure value

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and

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Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8